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WOLF, BLOCK, SCHORR & SOLIS-COHEN LLP 250 PARK AVENUE NEW YORK, NY 10177			EXAMINER GANGULY, RAJARSHI	
			ART UNIT 4153	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/535,383

Applicant(s)

LOSHAKOVE ET AL.

Examiner

Rajarshi Ganguly

Art Unit

4153

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,18,19,21,25,26,29-36,41,43,51,77 and 82-85 is/are pending in the application.
- 4a) Of the above claim(s) no claims is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,18,19,21,25,26,29-36,41,43,51,77 and 82-85 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.
2. Receipt is acknowledged of the preliminary amendments filed on May 16, 2005 and October 10, 2007 which papers have been placed of record in the file. Examiner has taken these preliminary amendments into consideration during examination.

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a) because in Figure 11C it is difficult to determine that the figure shows, "a plurality of nozzles fed by a separate tube" and instead seems to have six circles hovering in mid-air. Examiner requests that Figure 11C be clarified to show, "a plurality of nozzles fed by a separate tube." Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement

Art Unit: 4153

sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

2. The disclosure is objected to because of the following informalities: spelling and grammatical errors. For example when specification states, "...a controller which synchronizes a an activation of said vessel holder and delivery of said adhesive," (page 9, lines 1-2). Appropriate correction is required.
3. The abstract of the disclosure is objected to because the abstract repeats the language of the first claim verbatim and uses legal phraseology such as "said." Correction is required. See MPEP § 608.01(b).
4. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The

Art Unit: 4153

disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

### ***Claim Objections***

5. Claims 3,4,18,19, 21,25,26, and 51 are objected to because of the following informalities: claims 3 and 4 lack clear antecedent basis for "juxtaposed;" claims 18, 19 and 21 lack clear antecedent basis for "applying;" and claims 25, 26 and 51 lack clear antecedent basis for "removing." The examiner proposes that "said" be added before "juxtaposed," "applying," and "removing" to clarify proper antecedent basis. Claim 19 is also objected to because the second line of the claim has incorrect verb usage where it states, " which mold shapes the adhesive about said area." The examiner recommends using, "molds the adhesive about said area," or "which mold, shapes the adhesive about said area." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

7. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 as a dependant of claim 1, discloses a method which conflicts with the method disclosed in Claim 1; while Claim 1 states, "... and removing said juxtaposition device after said adhesive sufficiently sets;" however, claim 26 states, "...said removing comprises removing (said juxtaposition device) as soon as

Art Unit: 4153

said adhesive starts to sets.” As currently stated in the claims, it would be difficult to remove the same juxtaposition device at two different times; therefore claim 26 fails to further limit claim 1 and is rejected for being indefinite. However for the purposes of examination the examiner is interpreting, “ as soon as said adhesive starts to set” as occurring simultaneously or after “said adhesive sufficiently sets.”

***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 3-4, 18, 19, 29, 30, 31, 33-35, 43, 82, and 83 are rejected under 35 U.S.C. 102(b) as being anticipated by Popov et al., US 6068637 (hereinafter referred to as Popov).

10. Regarding claim 1, Popov discloses a method of performing an anastomosis comprising; juxtaposing two blood vessels to be anastomosed using an juxtaposition device (70 and 72), to a desired configuration in which at least one vessel (10) is an end vessel; applying an adhesive to said vessels while they are in said configuration, said adhesive (70c and 72c) being sufficient to ensure both sealing and bonding of said two vessels to each other; and removing said juxtaposition device after said adhesive sufficiently sets; wherein the juxtaposition device remains primarily external to at least

Art Unit: 4153

one of the vessels during the juxtaposing, (column 10 line 63 to column 11 line 14 and figures 10-11).

11. Regarding claims 3 and 4, Popov discloses a method according to claim 1 of inserting a part of his juxtaposition device (50) into the vessel and its wall (figure 6).

12. Regarding claim 18, Popov discloses a method according to claim 1, wherein applying comprises applying using a plurality of nozzles (70c and 72c) arranged in a ring, (column 10 line 63 to column 11 line 14 and figures 10-11).

13. Regarding claim 19, Popov discloses a method according to claim 1 wherein applying comprises applying into a mold adjacent said anastomosis area, which shapes the adhesive about said area, ((column 10 line 63 to column 11 line 14 and figures 10-11).

14. Regarding claim 29, Popov discloses a method, which comprises removing all foreign materials other than the adhesive, (column 11 lines 45-lines 57).

15. Regarding claim 30, Popov discloses a method of providing a strengthening element in an anastomosis site and leaving said strengthening element permanently in said anastomosis, (column 10 line 63 to column 11 line 14 and figures 10-11, examiner is interpreting "strengthening element" as a type of adhesive since when it cures it provides strength to the anastomosed area).

16. Regarding claims 31 and 33, Popov discloses a method of performing an anastomosis, comprising attaching at least a first external scaffold element (70) to a first blood vessel (10), wherein said first blood vessel is an end vessel (figures 10 and 11); attaching at least said first external scaffold element or a second external scaffold

Art Unit: 4153

element (72) to a second blood vessel (12), (figures 10-11); positioning said blood vessels using said at least a first scaffold element, to a desired configuration (figure 10-11); applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other; and removing said at least first external scaffolding element, (column 10 line 63 to column 11 line 14 and figures 10-11).

17. Regarding claims 34 and 35, Popov discloses a method according to claim 31, comprising mechanically attaching said at least first scaffolding element (14) to said first blood vessel; wherein mechanically attaching comprises piercing (30), (figure 2-4, column 9 line 50 to column 10 line 17, and column 10 line 63 to column 11 line 14, clips are being replaced with glue).

18. Regarding claim 43, Popov discloses a method according to claim 31, wherein said at least one scaffolding element comprises a balloon, (figure 19-20, column 15 line 33-44 and column 14 line 32-45).

19. Regarding claim 82, Popov discloses a method according to claim 1, wherein only one of said vessels (10) is an end vessel (figure 10-11, and column 10 line 63 to column 11 line 14 and figures 10-11).

20. Regarding claim 83, Popov discloses a method according to claim 1, wherein applying (the adhesive) is performed by the juxtaposition device, (figure 10-11 and column 10 line 63 to column 11 line 14).



***Claim Rejections - 35 USC § 103***

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

23. Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Popov in view of Detweiler (5141516). Popov discloses a method according to claim 1 wherein said (juxtaposition device) is removed once anastomosis is established. What Popov does not teach is removing said juxtaposition device before said adhesive "sets completely" and/or "starts to set." Detweiler discloses a method of performing an anastomosis, comprising; juxtaposing two blood vessels to be anastomosed using a juxtaposition device, to a desired configuration in which at least one vessel is an end vessel and removing said juxtaposition device after said adhesive sufficiently sets; wherein the juxtaposition device remains primarily internal to at least one of the vessels during the juxtaposing and is partially inserted into a wall of at least one of said vessels (column 6 line 51 – column 7 line 24) and a method of removing juxtaposition devices

Art Unit: 4153

before adhesive sets completely, wherein is stated the phrase "cured sufficiently" is not completely cured and the device is removed as soon as adhesive starts to set (column 7 lines 15-24). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Popov disclosure with the teaching in Detweiler to remove juxtaposition devices after adhesive is "cured sufficiently" in order to remove juxtaposition devices before the adhesive sets completely and as soon as adhesive starts to set.

24. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popov in view of Schenck et al, US 4553542. Popov discloses a method of performing an anastomosis, comprising attaching at least a first external scaffold element (70) to a first blood vessel (10), wherein said first blood vessel is an end vessel (figures 10 and 11); attaching at least said first external scaffold element or a second external scaffold element (72) to a second blood vessel (12), (figures 10-11); positioning said blood vessels using said at least a first scaffold element, to a desired configuration (figure 10-11); applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other; and removing said at least first external scaffolding element (column 10 line 63 to column 11 line 14 and figures 10-11). Popov does not explicitly disclose a method wherein first blood vessel is a side vessel. Schenck discloses a method where a first external scaffolding element is attached simultaneously to both side and end vessels, (figure 8, column 6 line 15-52). In light of the teachings it would have been obvious to

Art Unit: 4153

one having ordinary skill in the art at the time the invention was made to modify the external scaffolding in Popov, before applying the adhesive, with the teaching in Schenck to simultaneously attach external scaffolding to both side and end vessels.

25. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Popov in view of Black et al. (6245083) hereinafter referred to as Black. Popov discloses a method according to claim 31 wherein said at least one of said at least one scaffolding elements is removed once anastomosis is established. What Popov does not teach is, "removing said at least one of said at least one scaffolding elements before said adhesive sets." Black discloses a method similar to claim 31 except using internal scaffolding, wherein removing comprises removing at least one of said at least one scaffolding elements before said adhesive sets, (column 6 lines 51-57). In light of the obvious teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Popov disclosure with the teaching in Black to remove at least one of said at least one scaffolding elements before said adhesive sets.

26. Claims 1, 3,4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff et al. US6682540 (hereinafter referred to as Sancoff) in view of Bessler. Sancoff discloses a method of performing an anastomosis, comprising; juxtaposing two blood vessels to be anastomosed using a juxtaposition device, to a desired configuration in which at least one vessel is an end vessel and removing said

Art Unit: 4153

juxtaposition device after said adhesive sufficiently sets; wherein the juxtaposition device remains primarily external to at least one of the vessels during the juxtaposing and is partially inserted into a wall of at least one of said vessels. What Sancoff does not disclose is applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other. Alternatively, Sancoff applies sutures to said vessels while they are in said configuration. Bessler teaches that it is well known in the art to apply adhesive in place of sutures (Column 18 Lines 10-13). In light of the above of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Sancoff et al disclosure with the teaching in Bessler to apply adhesive at "said configuration" in place of sutures.

27. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff in view of Bessler and Redl et al., US 4631055 (hereinafter referred to as Redl). As stated earlier Sancoff and Bessler disclose a method according to claim 1. What Sancoff does not disclose is "applying (adhesive) using a plurality of nozzles arranged in a ring." Bessler discloses applying (adhesive) using a plurality of nozzles arranged in a ring but does not disclose a juxtaposition device external to the blood vessels (column 17 lines 62-65 and column 18 lines 53-57, figure 10A-C). Redl discloses a device comprising a plurality of nozzles to apply adhesive, (column 1 lines 12-18 and column 3 line 50 to column 4 line 10, Figures 1-4, conl is equivalent to a nozzle). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the

Art Unit: 4153

time the invention was made to modify the Sancoff et al disclosure with the teachings in Bessler and Redl to apply (adhesive) using a plurality of nozzles arranged in a ring.

28. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff in view of Bessler and Buijsrogge et al, "Sutureless coronary anastomosis with an anastomotic device and tissue adhesive in off-pump porcine coronary bypass grafting," (hereinafter referred to as Buijsrogge). As stated earlier Sancoff and Bessler disclose a method according to claim 1. While Bessler discloses that the adhesive is applied, he does not explicitly state a measured amount. Buijsrogge discloses a method comprising applying a pre-measured amount of adhesive (pg 790(2), Anastomotic Procedure, lines 13 to 25). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Sancoff et al disclosure with the teachings in Bessler and Buijsrogge to apply a pre-measured amount of adhesive to an anastomosis site.

29. Claims 31, 33-35, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff et al. US6682540 (hereinafter referred to as Sancoff) in view of Bessler. Regarding claims 31, Sancoff discloses a method of performing an anastomosis, comprising; attaching at least a first external scaffold element (150) to a first blood vessel wherein first blood vessel is a end vessel (55); attaching at least said first external scaffold element or a second scaffold element (140) to a second blood vessel (65); positioning said blood vessels using said at least a first external scaffold

Art Unit: 4153

element, to a desired configuration and removing said at least first scaffolding element (150), (Figures 21A-F and 22A-D) What Sancoff does not disclose is applying an adhesive to said vessels while they are in said configuration, said adhesive being sufficient to ensure both sealing and bonding of said two vessels to each other. Alternatively, Sancoff incorporates a scaffolding element (165), which comprises a plurality of wires (170) adapted to engage a blood vessel through piercing, in order to simultaneously place multiple sutures (Figures 21A-F and 22A-D). Bessler teaches that it is well known in the art to apply adhesive in place of suturing (Column 18 Lines 10-13). In light of the above teachings it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Sancoff et al disclosure with the teaching in Bessler et al to apply adhesive to the tissue ends in place of sutures after the plurality of wires have engaged the vessels through piercing.

30. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sancoff in view of Bessler and Buijsrogge. As stated earlier Sancoff and Bessler disclose a method according to claim 31. While Sancoff discloses scaffolding that is mechanically attached via hooking, he does not disclose using an adhesive to seal and bond vessels. Buijsrogge discloses using an adhesive to seal and bond vessels after incorporating a scaffolding element that is mechanically attached to blood vessel engagement region through hooking. In light of the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Sancoff et al disclosure with the teaching in Bessler et al to apply adhesive to the tissue ends in

Art Unit: 4153

place of sutures and to engage the vessels using a scaffolding with hooks before applying adhesive.

31. Claims 77, 84 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nicholas et al, (US 20010029384) in view of Popov. Nicholas discloses a first blood vessel holder (116a); a second blood vessel holder (116b) adapted to interlock with said first blood vessel holder such that blood vessels held by said two vessel holders contact (figures 2-8). Nicholas also discloses a method wherein only one of said vessels is an end vessel and wherein the first blood vessel holder and the second blood vessel holder are each substantially outside their respective blood vessels (figures 14-17). However Nicholas does not disclose an adhesive port on at least one of said first vessel holder and said second vessel holder, said port configured to deliver an adhesive to said contact at an external portion of the contact. Instead, Nicholas discloses a port on at least first vessel holder configured to deliver clips to said contact at an external portion of the contact (paragraph 85 line 1 to paragraph 87 line 11). Popov discloses a first blood vessel holder and a second blood vessel holder as well as an adhesive port on both vessel holders configured to deliver an adhesive to said contact at an external portion of the contact. Popov additionally discloses a method wherein only one of said vessels is an end vessel, wherein the first blood vessel holder and second blood vessel holder are each substantially outside their respective blood vessels (figures 10-11 and column 10 line 63 to column 11 line 14). Alternatively, Popov discloses a method wherein the adhesive ports (figures 10-11) on the vessel holders are replaced by clip delivery ports (figures 8-9) (column 10 lines 31-67). However Popov

Art Unit: 4153

does not disclose a means for the two vessel holders to interlock such that the two blood vessels contact. In light of the above teachings there is motivation for a person of ordinary skill in the art at the time the invention was made to modify the Nicholas disclosure with the teaching in Popov to deliver an adhesive to the contact point between vessels in place of clips.

### ***Conclusion***

32. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- a. Makower et al, US6071292,
- b. Schulze et al, US6860891 B2
- c. Wilk et al. US5254113
- d. Berg et al. US5972017

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rajarshi Ganguly whose telephone number is (571)-270-1891. The examiner can normally be reached on Mon-Thurs, 8:00a.m. To 5:00p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)-272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Art Unit: 4153

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*RG*

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10/04/07

GARY JACKSON  
SUPERVISORY PATENT EXAMINER

*Gary Jack*